IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
SOUTHWESTERN DIVISION
SPRINGFIELD

KATIE HARMAN Plaintiff, -vs- BREG, INC., a California Corporation Defendant.	)	Case No. _____ COMPLAINT JURY TRIAL DEMANDED

CIVIL COMPLAINT

COMES NOW the Plaintiff, Katie Harman, residing at 1218 W. Ridgecrest St., Ozark, Missouri, by and through Plaintiff's attorney, ALESHIRE ROBB, P.C., upon information and belief, and at all times hereinafter mentioned, alleges as follows:

INTRODUCTION AND SUMMARY OF ACTION

1. Pain pumps are medical devices that surgeons use to manage post-operative pain. Orthopedic surgeons used pain pumps after surgery to continuously infuse, via a catheter, a local anesthetic for several days directly into the joint.

2. The pain pumps first used in the 1990s had limited amounts of anesthetic and surgeons placed the pain pump catheter in the muscle or outside of the joint. Over the years, however, Defendant Breg began marketing their pain pumps to orthopedic surgeons and encouraging orthopedic surgeons to insert the pain pump catheter directly into the joint space or "intra-articular space".

3. Continuous infusion of local anesthetic directly into the joint can cause serious and permanent damage to the joint cartilage. The damage occurs when the local anesthetic kills

the chondrocytes (cartilage cells) and causes cartilage to degenerate progressively. Patients injured by pain pumps develop a condition called "chondrolysis," which is the complete or nearly complete loss of cartilage in the joint. It is an irreversible, disabling, and extremely painful condition. These patients typically require multiple additional surgeries, including with time, complete joint replacement.

4. Defendant Breg manufactured and marketed these devices without doing a single study to determine the safety of their pain pumps or what damage could be caused when orthopedic surgeons placed the pain pump catheter directly into the joint space/intra-articular space. Instead, the pain pump manufacturers encouraged orthopedic surgeons to use the pain pumps and local anesthetics, in tandem, in an untested and dangerous manner.

5. Breg sought approval from the United States Food and Drug Administration (hereinafter "FDA") for the placement of the pain pump catheter in the joint space/intra-articular space beginning in the late 1990s. The FDA *rejected* their applications for both orthopedic and intra-articular placement due to a lack of safety information. Yet, Breg chose not to advise physicians about the dangers associated with such use, not to tell physicians that the pain pump's safety for intra-articular use was untested, not to tell physicians that their FDA applications for use in the joint space were rejected, not to advise patients of the risks associated with use of the pain pump in the joint space, and continued to sell and market these pain pumps for use in the joint space with reckless indifference to the safety of the patients who would use their product - all to the detriment of thousands of patients generally and Plaintiff, Katie Harman, in particular.

6. On November 13, 2009, the FDA issued a directive in which it noted that pain pumps had never been cleared by the FDA for intra-articular use and that the pumps and the local anesthetics used in them were defective due to a failure to warn regarding the risk of

chondrolysis. The FDA directed pain pump manufacturers to include such warnings. The FDA further noted that the information on dose administration was insufficient in so far as there was no information about maximum daily dose or the dose appropriate for intra-articular use with pain pumps. Although this FDA directive was based upon reported adverse events of chondrolysis, this information was known or knowable by the pain pump manufacturers, including Defendant Breg, prior to the reports of these adverse events. This directive stated that pain pumps were not FDA approved to continuously infuse local anesthetic into the intra-articular space of human joints.

7. There are multiple, published, peer-reviewed studies demonstrating the toxic effects of local anesthetics commonly used in pain pumps on joint cartilage. By late 2005 and early 2006, the pain pump industry knew that Dr. Charles L. Beck, an orthopedic surgeon, was reporting to the scientific and medical community some very disturbing findings. He found a significant number of his patients developed chondrolysis following the intra-articular placement of a pain pump catheter and subsequent continuous infusion of local anesthetic into the joint for several days. Dr. Beck associated these injuries with the intra-articular use of pain pumps.

8. Dr. David Bailie, Breg's own paid medical consultant, contacted Breg on March 29, 2006, advising them of cases of chondrolysis he was seeing in his practice and that he strongly suspected a link between the intra-articular pain pumps and chondrolysis. Dr. Bailie implored Breg to conduct studies and offered to assist them in those studies. Breg declined to run any studies because they felt the studies would not help them sell more pain pumps. No safety studies of their pain pumps effects on cartilage were ever conducted by Breg.

9. Had Breg conducted the simple science studies Dr. Bailie suggested and that the FDA required back in the 1990s, as they were obligated to do, they would easily have

determined that exposure to the local anesthetics commonly used in pain pumps over time in the joint is exceedingly dangerous and contraindicated. Had they performed the appropriate tests timely, the Plaintiff's orthopedic surgeon would not have used a pain pump catheter in the joint space and Plaintiff, Katie Harman, would not have suffered the devastating effects of chondrolysis in her left shoulder.

JURISDICTION AND VENUE

10. The Court has original jurisdiction under 28 U.S.C. § 1332 as the parties are citizens of different states and the amount in controversy between the parties exceeds the sum of $75,000, exclusive of interests and costs.

11. The Court has personal jurisdiction over the Defendant because the Defendant transacts business in and thereby maintains sufficient minimum contacts with this judicial district and further the wrongs complained of herein arose in the Western District of Missouri.

12. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(a)(2) because, inter alia, the Defendant regularly solicit and engage in business and other persistent courses of conduct and derive substantial revenues from goods used in the state of Missouri and the substantial part of the events or omissions giving rise to this claim occurred in the Western District of Missouri. Many witnesses, including medical witnesses, are located in the Western District of Missouri.

PARTIES

13. Plaintiff, Katie Harman, is and was at all times relevant herein, a resident and citizen of Missouri. On or about March 21, 2008, the catheter for a Breg PainCare 3000 pump that was manufactured and/or placed into the stream of commerce by the Defendant was implanted into Plaintiff Katie Harman's left shoulder.

14. Defendant Breg, Inc. (hereinafter referred to as "Breg" or "Defendant") is a California corporation with their principal place of business in Vista, California. Breg designs, manufactures and develops pain pumps. At all times relevant hereto, Breg was authorized to conduct business in the State of Missouri. At all times relevant hereto, Breg engaged in the testing, manufacturing, labeling, distributing, marketing, promoting and selling of pain pumps in the State of Missouri.

FACTUAL BACKGROUND

A. Case Specific

15. On March 21, 2008, Plaintiff Katie Harman, a 20 year old woman, underwent an arthroscopic capsulorrhaphy surgery on her left shoulder at St. John's Regional Health Center in Springfield, Missouri. The surgery was performed by Dr. Victor Wilson, an orthopedic surgeon. At the time of the surgery, Dr. Wilson noted that the articular surfaces of the shoulder joint were normal. Following this surgery, Dr. Wilson implanted a catheter in the Plaintiff's left shoulder joint for a PainCare 3000 (hereinafter "Breg pain pump") to continuously infuse local anesthetic into the shoulder joint. The Breg pain pump continuously infused 100 mL of 0.5% Marcaine without epinephrine, at the rate of 2.0 mL/hr into the Plaintiff's shoulder joint for 48 hours following the surgery.

16. Plaintiff Katie Harman initially progressed as expected. However, after the pain of the healing process began to wane, a new and different pain set in. Plaintiff's shoulder continued to deteriorate while she tried to finish her education and training as a physical therapist, causing Plaintiff continual and constant pain and restriction. On March 20, 2014, Katie Harman went to Dr. Wilson for evaluation of her left shoulder. Dr. Wilson did a detailed review of Ms. Harman's medical records and a thorough physical exam and conducted imaging studies.

He diagnosed Ms. Harman with Post Arthroscopic Glenohumeral Chondrolysis (PAGCL) caused by the Breg pain pump used in her 2008 surgery.

17. Plaintiff Katie Harman did not discover that the loss of cartilage and narrowing of the joint space was associated with the use of the Breg pain pump to continuously infuse 100 mL of 0.5% Marcaine without Epinephrine into her shoulder joint after her March 21, 2008 surgery until March 20, 2014 when her doctor informed her of her diagnosis and that the Breg pain pump had caused the injury.

18. The continuous infusion of local anesthetics over time directly into Plaintiff Katie Harman's shoulder joint after her March 21, 2008 surgery caused her serious and permanent cartilage damage. As a result, the Plaintiff suffered a narrowing of the joint space and/or a condition called "chondrolysis," which is the complete or nearly complete loss of cartilage in the joint. This is an irreversible, disabling and extremely painful condition. Plaintiff Katie Harman currently has and will continue to have difficulty doing the most basic tasks of everyday living.

19. Plaintiff Katie Harman has undergone conservative treatment but with little to no effect. She will require additional surgery, including a total shoulder replacement, as a result of the narrowing of the joint space and/or chondrolysis caused by the dangerously defective pain pump and the local anesthetic contained therein. Her daily life is consumed with the devastation of a destroyed shoulder and the prospects of a life of pain and medication. The Plaintiff has trained for and now is a physical therapist and will suffer lost income, loss of career options, a loss of enjoyment of life and other damages, all of which were avoidable.

B. Breg's Misconduct

20. Breg misled both the medical community and the public at large, including the Plaintiff Katie Harman and her orthopedic surgeon Dr. Wilson, by making false representations

about the safety of their products and concealing the fact that the product was not FDA approved for use by orthopedic surgeons and not in the joint space. Breg downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects associated with the intra-articular use of their pain pumps, including chondrolysis, despite information available before March 21, 2008 demonstrating that these pain pumps were likely to cause such serious injury to the users.

21. Breg did not conduct any testing to determine whether intra-articular use of their pain pumps would be safe. Nor did Breg conduct a reasonable search of the available medical literature to see whether commonly and foreseeably used local anesthetics, like Marcaine, were toxic to joint cartilage (cytotoxic).

22. In July 2000, without conducting any tests or studies for safety, Breg added the PainCare 3000, to its inventory. The PainCare 3000 increased the size of the reservoir from 50cc in previous models to 100cc.

23. Breg sought FDA clearance for an indication for use by orthopedic surgeons in the intra-articular space. Breg knew that the FDA refused to approve such indications for use without data showing safety and effectiveness. On September 19, 2000, the FDA cleared Breg's pain pump application, but the clearance did not include Breg's request for use of their pain pumps by orthopedic surgeons and did not include use in the intra-articular (joint) space.

24. Breg did not notify orthopedic surgeons that the safety of the use of their pain pumps to continuously infuse commonly used local anesthetics into the joint space was unknown, had not been studied and had not been tested by Breg. Yet, Breg and their sales representatives promoted their pain pumps for use in the joint space. Breg's own consultant and an orthopedic surgeon, has testified numerous times, that when the Breg pain pump first came

out, the Breg sales representatives would approach doctors in the operating room and encourage them to use the devices intra-articularly in the shoulders.

25. Breg's business is and always has been, exclusively within the orthopedic arena.

26. Breg made Plaintiff Katie Harman and other patients like her unknowing, unwilling and unconsenting test subjects of the safety of the intra-articular use of their pain pumps to continuously infuse commonly used local anesthetics.

27. Even after Breg was notified of dozens of cases of cartilage injury associated with the intra-articular use of a pain pump to continuously infuse a local anesthetic by their own orthopedic consultant in 2005 and 2006, Breg chose to do nothing except to continue marketing and selling their pain pumps for orthopedic use, for well more than one year after being advised of this information. Breg further did not enter any of these cases into Breg's complaint database.

28. As a direct and proximate result of Breg's misconduct, Plaintiff Katie Harman suffered and will continue to suffer injuries, damages, and losses as alleged herein.

STATUTE OF LIMITATIONS AND FRAUDULENT CONCEALMENT

29. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts by Breg, as alleged herein. The Plaintiff Katie Harman and her orthopedic surgeons were kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiff Katie Harman could not reasonably have discovered the dangerous nature of and the unreasonable adverse side effects associated with the intra-articular use of pain pumps to continuously infuse commonly used local anesthetics into the joint prior to her becoming aware of the possible link between the two in March 2014.

30. Breg is and was under a continuing duty to disclose the true character, quality and nature of their pain pumps.

31. Breg knew that their pain pumps were not approved for use in orthopedics and not approved for intra-articular use (use in the joint) and that their pain pumps were being used in the joint, as shown by the following:

a. Breg attempted to gain FDA approval for use of its pain pumps in the joint space in November 1998, August 2000, September 2001 and February 2004. At each of those times, Breg indicated that it knew that the FDA had required the original manufacturer of the predicate device for Breg's pain pumps to remove such an indication from its label.

b. The FDA approved Breg's pain pump on September 19, 2001, but this clearance did not include the requested indication for use in the joint space or by orthopedic surgeons.

32. Undaunted, Breg fully intended to and did market its pain pumps to orthopedic surgeons, including the Plaintiff's orthopedic surgeon, Dr. Wilson, to continuously infuse commonly used local anesthetics into the joint space, despite the FDA's denial of such an indication.

33. As early as 2001, Breg fraudulently concealed the dangerous nature of its pain pumps by withholding the information regarding the FDA's denial of the orthopedic, intra-articular and/or within a joint indications from its sales representatives and the orthopedic surgeons who used the pain pumps. Breg withheld this information knowing that its pain pumps were being designed and marketed for use in the joint space. For example, in a June 2007 Breg held a sales representative training in Vista, California. The PowerPoint slides used to educate sales reps on placement of the catheter, plainly indicate "place at the origin of pain… in the joint".

34. Breg's marketing product manager knew that orthopedic surgeons were using the Breg pain pump intra-articularly and Breg's regulatory director knew that this was not a cleared indication for use.

35. Breg fraudulently concealed the dangerous nature of its pain pumps from consumers and the medical community when Pat Cawley, Breg's vice president of Medical Research affirmatively stated in a July 2006 internal email that they had to "quell some of the hysteria" among orthopedic surgeons reporting injuries from the Breg pain pumps. On August 11, 2006 Mr. Cawley sent another internal email when he returned from a medical symposium where he had tried to "plant a seed of doubt" that their pumps were injuring patients. On March 29, 2006, Breg's head of marketing rejected their consulting orthopedic doctor's suggestion to conduct safety studies stating "I have no interest in supporting this study…I don't believe it will help us sell any additional products."

36. Federal law requires Breg to follow-up and investigate the injuries reported by Dr. Bailie and other orthopedic surgeons, including getting specific information, including dates of events, the specific injury, how the product was being used, how the patient was doing, and if follow-up treatment was needed. However, Breg failed to any of this.

37. In 2007, Breg finally prepared a form letter to doctors regarding chondrolysis. However, the letter mischaracterized the dangers of the pain pumps when used in the joint space by indicating that no clinical studies directly linked the pain pumps to chondrolysis. The letter failed to state that the FDA never would have approved such a study given the lack of safety as there was already extensive literature and in vitro research indicating that such use was unsafe. The letter also mischaracterized Breg's pain pumps by stating that the pain pumps were not indicated for intra-articular delivery without stating that such use had been specifically denied by

the FDA. Finally, as far as the record shows, Breg did not send the letter out to physicians, unless and until a physician requested it.

38. Breg failed to provide adequate and effective warning that would alert an orthopedic surgeon of the dangers of using their pain pumps. In October 2006, Breg began placing a warning card in the boxes that contain the pain pumps. These boxes were received at hospitals, not the orthopedic surgeon's offices, and were unpacked by hospital staff that assembled the pumps in the perioperative field and then handed the pump to the surgeon to place. There was no chance that an orthopedic surgeon would see this warning and Breg knew as much.

COUNT I
STRICT PRODUCTS LIABILITY

39. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

40. Because of the above described concealment by Breg of the true character, quality and nature of its pain pumps, Breg is estopped from relying on any statute of limitations defense.

41. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

42. In the course of business, the Defendant, Breg Inc., manufactured and/or distributed Breg pain pumps and placed them into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

43. At the time of sale, the Breg pain pump was unreasonably dangerous when used in the joint space as reasonably anticipated, marketed and instructed by Breg beyond the extent contemplated by ordinary patients and ordinary orthopedic surgeons with ordinary knowledge

regarding the device and without knowledge of its dangerous characteristics, as the foreseeable risks associated with its design exceeded the benefits associated with that design, as evidenced by one or more of the following particulars:

a. The labeling failed to instruct or warn the U.S. medical community that the safety of the device had not been established for use in the intra-articular (joint) space;

b. The labeling failed to disclose to the U.S. medical community that continuous infusion of commonly used local anesthetics, such as Marcaine, with or without Epinephrine, in high volumes, over two days or more, into the joint space, may cause serious and permanent injury to the joint cartilage;

c. The labeling failed to include a precaution against placing the catheter of the pain pump directly in the joint space;

d. The labeling failed to provide to the U.S. medical community adequate instructions for the safe use of the device, failing specifically to identify quantities, flow rates and types of local anesthetic medications that could be safely and effectively used for continuous infusion of the joint space;

e. The labeling failed to disclose to the U.S. medical community that the effectiveness of the device was uncertain for use directly in the joint space;

f. The labeling failed to disclose to the U.S. medical community that the FDA had considered requests to add the use of the pain pump in a joint space as an indication for use in pain pump labels, but would not clear the addition of this use of pain pumps;

g. The labeling failed to disclose that commonly used local anesthetics that were reasonably foreseeable and intended to be used with the pain pump were not approved by the FDA for continuous infusion into the joint;

h. The pain pump was designed to continuously infuse foreseeable and commonly used local anesthetic medications known to be associated with damage to articular cartilage directly into the joint;

i. When used as designed, the pain pump continuously infused, over time, dangerously high doses of local anesthetic directly into the joint and thereby caused chondrolysis;

j. The foreseeable risks of such use exceeded the benefits associated with the design and/or formulation of the product; and

k. Alternative catheter placements were available which would have limited and/or prevented the risk of development of chondrolysis following use of a pain pump.

44. Breg knew or in the exercise of reasonable care should have known of the danger of chondrolysis posed by the use of its pain pump to continuously infuse the joint space with commonly used local anesthetics.

45. Breg was required to warn about the danger of chondrolysis posed by the foreseeable use of its pain pump to continuously infuse the joint space with commonly used local anesthetics.

46. Breg failed to provide an adequate warning that a manufacture exercising reasonable care would have issued to Plaintiff Katie Harman or her orthopedic surgeon at the time the Breg pain pump was manufactured, distributed and sold in that in light of the ordinary knowledge common to members of the community who use Breg pain pumps; Breg failed to:

a. Issue, distribute and/or include a warning that was designed to reasonably catch the attention of an orthopedic surgeon or of the end user of the pain pump;

b. Issue, distribute and/or include a warning that was understandable by an orthopedic surgeon or the end user of the pain pump;

c. Issue, distribute and/or include a warning that fairly indicated the danger from the foreseeable use of the pain pump in or near the joint space;

d. Issue, distribute and/or include a warning that was sufficiently conspicuous to match the magnitude of the danger posed by the use of the pain pump in or near the joint space;

e. Issue, distribute and/or include a warning that disclosed that the effectiveness of the device was uncertain for use in the joint space;

f. Issue, distribute and/or include a warning that the local anesthetics commonly used and intended to be used in pain pumps were not approved by the FDA for continuous infusion into the joint;

g. Issue, distribute and/or include a warning that the FDA had considered requests by pain pump manufacturers, including Breg, to include use in the joint space as an indication for use in the pain pump labeling and then had rejected indications for use of pain pumps to deliver local anesthetics directly into the joint space; and

h. Issue, distribute and/or include a warning that when used as designed and directed by Breg, the pain pump delivered over time dangerously high doses of local anesthetic directly into the joint.

47. The Breg pain pump was defective due to inadequate warning and/or inadequate clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting regarding the results of such trials, testing and study.

48. The Breg pain pump was further defective due to inadequate post-marketing warning or instruction, because, after Breg knew or in the exercise of reasonably care should

have known of the risk of chondrolysis associated with their pain pumps when used to continuously infuse local anesthetic into the joint space, Breg failed to provide the adequate post-marketing warnings that a manufacturer exercising reasonable care would have issued to the U.S. medical community and patients regarding chondrolysis. Rather, Breg continued to promote the Breg pain pump as safe and effective for such use.

49. Plaintiff Katie Harman's orthopedic surgeon, Dr. Wilson, used the Breg pain pump in the joint space in a manner reasonably anticipated, marketed and instructed by Breg.

50. As a direct and proximate result of the Breg pain pump being sold without an adequate warning, Plaintiff Katie Harman suffered those injuries and damages as described with particularity below.

51. The failure to warn alleged above was a foreseeable and substantial contributing cause of the injuries suffered by Plaintiff Katie Harman. Specifically, the Breg pain pumps caused Plaintiff to suffer the permanent loss of cartilage in her left shoulder and the narrowing of the left shoulder joint space, resulting in severe pain and discomfort of the shoulder, loss of use and function of the shoulder, and additional required surgery. The use of the pain pump also rendered the therapeutic benefits of her prior shoulder surgery worthless and of no value. Plaintiff Katie Harman will also require future medical care, including with time a total shoulder replacement. In addition, Plaintiff has suffered, and will continue to suffer, pain, anxiety, mental distress and anguish, and permanent impairment of the use and function of the affected shoulder.

WHEREFORE, Plaintiff states that she has been damaged, for which damage she prays judgment against Defendant Breg Inc., in such sum as may be fair and reasonable in the premises, together with her costs in this behalf expended.

COUNT II
Breach of Implied Warranty of Fitness

52. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

53. By intentionally promoting and knowingly selling the Breg pain pump for use in continuously infusing commonly used local anesthetics into the joint space following orthopedic surgery, the Defendant, Breg Inc., impliedly warranted to Plaintiff Katie Harman and her orthopedic surgeon that the Breg pain pump was merchantable, proven safe and effective for such use, was properly labeled, and contained proper instructions for its intended use.

54. This implied warranty extended to Plaintiff Katie Harman as the ultimate consumer and user of the Breg pain pump.

55. Breg breached its implied warranty to Plaintiff Katie Harman in that the pain pump was unmerchantable, was not safe for use in continuously infusing commonly used local anesthetics into the joint space following orthopedic surgery, and was unreasonably dangerous when used to continuously infuse commonly used local anesthetics into the joint space as such use can cause chondrolysis.

56. As a direct and proximate result of Breg's breach of implied warranty, Plaintiff Katie Harman will require future medical care, including additional shoulder surgery with time including, but not limited to, total shoulder replacement. In addition, the Plaintiff has suffered, and will continue to suffer, pain, anxiety, mental distress, and anguish, and permanent impairment of the use and function of the affected left shoulder extremity.

WHEREFORE, Plaintiff states that she has been damaged, for which damage she prays judgment against Defendant Breg Inc., in such sum as may be fair and reasonable in the premises, together with her costs in this behalf expended.

COUNT III
Negligence

57. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

58. At all times relevant to this action, the Defendant, Breg Inc., had a duty to exercise reasonable care, and to comply with the existing standards of care, in their preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion, and sale of the pain pumps and the local anesthetics used in the pumps, which the Defendant introduced into the stream of commerce, including a duty to ensure that users would not suffer from unreasonable, dangerous or untoward adverse side effects.

59. At all times relevant to this action, Breg had a duty to warn all health care providers and consumers of the risks, dangers, and adverse side effects of pain pumps and the local anesthetics used in the pumps.

60. At all relevant times, Breg knew or reasonably should have known that the Breg pain pumps were unreasonably dangerous and defective when used as directed and as designed. A reasonably careful search and review of the scientific and medical literature, and other information, should have indicated to Breg that:

a. Commonly used local anesthetics likely to be used in pain pumps were harmful to human and animal articular cartilage when infused continuously over time and that toxicity to cartilage increased with the duration of exposure;

b. Commonly used local anesthetics likely to be used in pain pumps were not approved by the FDA for continuous infusion into the joint space;

c. Use of any pain pump to deliver local anesthetic to or near the joint space had not been cleared by the FDA, and, in fact, had been specifically rejected by the FDA;

d. Continuous infusion of local anesthetics, through a catheter, directly into or near the cartilage of a joint, for two days or more, had not been adequately tested for safety or efficacy; and

e. The risk of narrowing of the joint space, chondrolysis and other serious post operative problems associated with using the pain pump as designed and instructed by Breg outweighed the possible benefits of such use.

61. Based on what Breg knew or reasonably should have known as described above, Breg deviated from principles of due care, deviated from the standard of care, and were otherwise negligent in one or more of the following particulars:

a. In failing to conduct the tests and studies necessary to determine that the use of pain pumps to continuously infuse local anesthetic directly into the joint was dangerous to joint cartilage and contraindicated for use;

b. In failing to instruct or warn the U.S. medical community that the safety of the device had not been established for use in the joint space;

c. In failing to disclose to the U.S. medical community that the local anesthetics that were commonly and intended to be used in their pain pumps were not approved by the FDA for continuous infusion into the joint.

d. In failing to disclose to the U.S. medical community that continuous infusion of commonly used local anesthetics such as Marcaine, with or without epinephrine, over two days or more, into the joint space, may cause serious and permanent injury to the joint cartilage;

e. In failing to include a precaution against placing the catheter of the pain pump directly into or near the joint space;

f. In failing to provide to the U.S. medical community adequate instructions for the safe use of the devices, specifically failing to identify quantities, flow rates and types of local anesthetic medication that could be safely and effectively used in the joint;

g. In failing to disclose to the U.S. medical community that the effectiveness of the device was uncertain for use directly in the joint space;

h. In failing to disclose to the U.S. medical community that the FDA had considered requests to add the use of the pain pump in the joint space as an indication for use in pain pump labels, but would not clear the addition of this use of pain pumps;

i. In failing to disclose to the U.S. medical community that no tests had ever been done to determine the safety of using the pain pump in the joint;

j. Designing and manufacturing a device to be used to directly and continuously infuse into the joint commonly used local anesthetics associated with damage to joint cartilage;

k. Designing and manufacturing a product designed to deliver, over time, dangerously high doses of local anesthetic drugs directly into the joints;

l. Failing to recall the pain pumps;

m. Failing to provide adequate post-marketing warnings and instructions to physicians and medical providers using the pain pumps; and

n. Promoting and marketing the pain pumps for use in the joint space after the FDA had considered and rejected such an indication for use.

62. Had Breg performed those tests and studies necessary to determine that pain pumps and local anesthetics should not be used directly in the joint before Plaintiff Katie Harman's orthopedic surgeon, Dr. Wilson, used a pain pump following her shoulder surgery, as they were required to do, the Plaintiff would not have used a Breg pain pump in the joint space

and would not have developed chondrolysis and suffered the injuries and damages described with particularity above.

63. Breg is directly liable for the negligent conduct of their actual and/or ostensible employees, servants, and agents, who include, but not limited to, their sales representatives. The negligent conduct of these employees, servants, and actual and/or ostensible agents, jointly and severally, caused and/or increased the risk of harm of, and the grievous injuries and damages sustained by Plaintiff Katie Harman.

64. The negligent acts and omissions alleged above were foreseeable and substantial factors that caused the injuries suffered by Plaintiff Katie Harman, which would not have occurred but for the use of the Breg pain pump. Specifically, the Breg pain pump when used as designed and marketed by Breg directly and proximately caused the Plaintiff to suffer the permanent loss of cartilage in her shoulder joint and narrowing of the joint, resulting in severe pain and discomfort of the shoulder, loss of use and function of the shoulder and arm, and requiring additional surgery, including with time a total shoulder replacement. The use of the Breg pain pump also rendered the therapeutic benefits of her prior shoulder surgery worthless and of no value. Plaintiff Katie Harman will also require future medical care. In addition, the Plaintiff has suffered, and will continue to suffer, pain, anxiety, mental distress and anguish and permanent impairment of the use and function of her affected right lower extremity.

WHEREFORE, Plaintiff states that she has been damaged, for which damage she prays judgment against Defendant Breg Inc., in such sum as may be fair and reasonable in the premises, together with her costs in this behalf expended.

COUNT IV
Missouri Merchandising Practices Act

65. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

66. The Missouri Merchandising Practices Act ("MMPA") was enacted to preserve fundamental honesty, fair play, right dealings, and to protect Missouri consumers.

67. The MMPA is interpreted broadly to achieve the above listed policy goals.

68. The MMPA prohibits the use or employment by any person of any deception, fraud, false pretense, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of material facts in connection with the sale or advertisement of any merchandise in trade or commerce. RSMo. 407.020.

69. The MMPA authorizes a private cause of action to any person who purchases or leases merchandise for personal, family or household purposes and thereby suffers ascertainable loss of money or damages as a result of the above listed prohibited acts and omissions. RSMo. 407.025.

70. Defendant Breg committed acts prohibited by the MMPA in that it used and employed deception, fraud, false pretense, false promise, misrepresentation, unfair practice, the concealment, suppression, or omission of material facts in connection with the sale or advertisement of any merchandise in trade, including, but not limited to, the following acts or omissions:

a. The labeling failed to instruct or warn the U.S. medical community that the safety of the device had not been established for use in the intra-articular (joint) space;

b. The labeling failed to disclose to the U.S. medical community that continuous infusion of commonly used local anesthetics, such as Marcaine, with or without

Epinephrine, in high volumes, over two days or more, into the joint space, may cause serious and permanent injury to the joint cartilage;

c. The labeling failed to include a precaution against placing the catheter of the pain pump directly in the joint space;

d. The labeling failed to provide to the U.S. medical community adequate instructions for the safe use of the device, failing specifically to identify quantities, flow rates and types of local anesthetic medications that could be safely and effectively used for continuous infusion of the joint space;

e. The labeling failed to disclose to the U.S. medical community that the effectiveness of the device was uncertain for use directly in the joint space;

f. The labeling failed to disclose to the U.S. medical community that the FDA had considered requests to add the use of the pain pump in a joint space as an indication for use in pain pump labels, but would not clear the addition of this use of pain pumps;

g. The labeling failed to disclose that commonly used local anesthetics that were reasonably foreseeable and intended to be used with the pain pump were not approved by the FDA for continuous infusion into the joint;

h. The pain pump was designed to continuously infuse foreseeable and commonly used local anesthetic medications known to be associated with damage to articular cartilage directly into the joint;

i. When used as designed, the pain pump continuously infused, over time, dangerously high doses of local anesthetic directly into the joint and thereby caused chondrolysis;

j. The foreseeable risks of such use exceeded the benefits associated with the design and/or formulation of the product;

k. Alternative catheter placements were available which would have limited and/or prevented the risk of development of chondrolysis following use of a pain pump;

l. Issue, distribute and/or include a warning that was designed to reasonably catch the attention of an orthopedic surgeon or of the end user of the pain pump;

m. Issue, distribute and/or include a warning that was understandable by an orthopedic surgeon or the end user of the pain pump;

n. Issue, distribute and/or include a warning that fairly indicated the danger from the foreseeable use of the pain pump in or near the joint space;

o. Issue, distribute and/or include a warning that was sufficiently conspicuous to match the magnitude of the danger posed by the use of the pain pump in or near the joint space;

p. Issue, distribute and/or include a warning that disclosed that the effectiveness of the device was uncertain for use in the joint space;

q. Issue, distribute and/or include a warning that the local anesthetics commonly used and intended to be used in pain pumps were not approved by the FDA for continuous infusion into the joint;

r. Issue, distribute and/or include a warning that the FDA had considered requests by pain pump manufacturers, including Breg, to include use in the joint space as an indication for use in the pain pump labeling and then had rejected indications for use of pain pumps to deliver local anesthetics directly into the joint space;

s. Issue, distribute and/or include a warning that when used as designed and directed by Breg, the pain pump delivered over time dangerously high doses of local anesthetic directly into the joint;

t. Commonly used local anesthetics likely to be used in pain pumps were harmful to human and animal articular cartilage when infused continuously over time and that toxicity to cartilage increased with the duration of exposure;

u. Commonly used local anesthetics likely to be used in pain pumps were not approved by the FDA for continuous infusion into the joint space;

v. Use of any pain pump to deliver local anesthetic to or near the joint space had not been cleared by the FDA, and, in fact, had been specifically rejected by the FDA;

w. Continuous infusion of local anesthetics, through a catheter, directly into or near the cartilage of a joint, for two days or more, had not been adequately tested for safety or efficacy;

x. The risk of narrowing of the joint space, chondrolysis and other serious post operative problems associated with using the pain pump as designed and instructed by Breg outweighed the possible benefits of such use;

y. In failing to conduct the tests and studies necessary to determine that the use of pain pumps to continuously infuse local anesthetic directly into the joint was dangerous to joint cartilage and contraindicated for use;

z. In failing to instruct or warn the U.S. medical community that the safety of the device had not been established for use in the joint space;

aa. In failing to disclose to the U.S. medical community that the local anesthetics that were commonly and intended to be used in their pain pumps were not approved by the FDA for continuous infusion into the joint;

bb. In failing to disclose to the U.S. medical community that continuous infusion of commonly used local anesthetics such as Marcaine, with or without epinephrine, over two days or more, into the joint space, may cause serious and permanent injury to the joint cartilage;

cc. In failing to include a precaution against placing the catheter of the pain pump directly into or near the joint space;

dd. In failing to provide to the U.S. medical community adequate instructions for the safe use of the devices, specifically failing to identify quantities, flow rates and types of local anesthetic medication that could be safely and effectively used in the joint;

ee. In failing to disclose to the U.S. medical community that the effectiveness of the device was uncertain for use directly in the joint space;

ff. In failing to disclose to the U.S. medical community that the FDA had considered requests to add the use of the pain pump in the joint space as an indication for use in pain pump labels, but would not clear the addition of this use of pain pumps;

gg. In failing to disclose to the U.S. medical community that no tests had ever been done to determine the safety of using the pain pump in the joint;

hh. Designing and manufacturing a device to be used to directly and continuously infuse into the joint commonly used local anesthetics associated with damage to joint cartilage;

ii. Designing and manufacturing a product designed to deliver, over time, dangerously high doses of local anesthetic drugs directly into the joints;

jj. Failing to recall the pain pumps;

kk. Failing to provide adequate post-marketing warnings and instructions to physicians and medical providers using the pain pumps; and

ll. Promoting and marketing the pain pumps for use in the joint space after the FDA had considered and rejected such an indication for use.

71. Plaintiff suffered ascertainable loss as a result of Defendant's violations of the MMPA.

72. Defendant's conduct and actions in violating the MMPA were committed with deliberate indifference to and conscious disregard for the rights of Plaintiff and others sufficient to justify an additional award of punitive damages to punish Defendant's and deter Defendant and others from future conduct.

73. Plaintiff is entitled to her reasonable attorney's fee pursuant to RSMo. 407.025.1.

WHEREFORE, Plaintiff states that she has been damaged, for which damage she prays judgment against Defendant Breg Inc., in such sum as may be fair and reasonable in the premises, together with her costs in this behalf expended.

COUNT V
(Punitive Damages – Defendant Breg)

74. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

75. Defendant Breg engaged in a prolonged, wanton and malicious course of conduct, with conscious and deliberate disregard of a serious risk to the health, safety, rights, and interest of plaintiff and many other patients like her, in one or more of the following respects:

a. Defendant Breg knew that the FDA had repeatedly refused to clear an indication for use of its pain pumps in the joint space and not cleared for orthopedic use, but defendants failed to disclose to the medical community that the FDA did not clear pain pumps for intra-articular infusion following orthopedic surgery;

b. Defendant Breg failed to undertake the necessary research, analysis, and testing to determine the safety of intra-articular pain pump infusions before distributing their pain pumps, even though it knew and intended that the pumps would be used in this manner. Defendant failed to disclose to the medical community that the safety of using pain pumps within the joint space was untested and uncertain;

c. Defendant Breg failed to disclose to the U.S. medical community that intra-articular placement of its pain pumps was an "off-label" use which had never been approved or cleared by the FDA;

d. Defendant Breg conducted clinical "field" trials of its pain pumps in patients undergoing orthopedic arthroscopic shoulder procedures without first obtaining FDA authorization to conduct investigational clinical studies as an Investigational Device Exemption ("IDE"). In violation of FDA regulations, defendant Breg conducted these clinical trials without oversight or approval by an Institutional Review Board, and without disclosing in patient Informed Consent forms that the FDA did not clear pain pumps for intra-articular placement. To the contrary, defendant Breg reassured patients that its pain pumps were safe and "not experimental."

e. Defendant Breg actively promoted its pain pumps to orthopedic surgeons, instructing them that the pain pump catheters could safely be placed within the shoulder joint space, despite its knowledge that intra-articular placement was never an FDA-cleared indication

for use and was, in fact, an off-label use. Defendant also promoted its pain pumps in this manner despite knowing that there was no reliable data to support the safety of pain pump infusions inside the joint space;

f. Between 2005 and 2007, defendant Breg received numerous reports of patients who had suffered chondrolysis following intra-articular use of pain pumps, but Defendant Breg chose not to follow up on these reports or to warn surgeons about the possible link between pain pump infusions and chondrolysis. Instead Defendant Breg discredited the reports and downplayed their significance;

g. Defendant Breg failed to disclose to its own sales force: (1) that the FDA repeatedly rejected its applications for intra-articular or orthopedic indications for use of the pain pumps within the joint space; and (2) the rising number of reports of patients who had suffered injury to their cartilage following intra-articular pain pump infusions;

h. Defendant Breg turned down requests to help fund studies by outside scientists to investigate the potential association between intra-articular pain pump infusions and joint cartilage toxicity, on the grounds that such studies would not be good for sales;

i. Defendant Breg did not send "Dear Doctor" letters to orthopedic surgeons alerting them to newly inserted chondrolysis warnings in the pain pump product inserts, even though it had reason to know that surgeons were not aware of this labeling change.

76. Defendant Breg put its own profits ahead of a serious risk of harm to the health, safety and well-being of Plaintiff and many other unsuspecting patients. As a direct result, Plaintiff and others like her suffered serious and permanent injury to their shoulders, as well as a lifetime of relentless pain. The actions or omission of Breg that caused or contributed to cause the injuries were committed with complete indifference and/or conscious disregard for the rights

and safety of its customers, including plaintiff, entitling her to an award of punitive damages, in such sum as to punish and deter Breg and others from such conduct in the future.

WHEREFORE, Plaintiff, as to all Counts, prays for judgment in her favor and against Defendant, in a reasonable amount as determined by a jury, for:

a. Compensatory damages;

b. Punitive damages; and

c. Her reasonable costs and disbursements incurred herein, including any attorney fees incurred in prosecuting this action and recoverable at law; and any pre- or post-judgment interest recoverable at law, and for any other further relief as justice and equity desire.

JURY TRIAL DEMAND

Plaintiff hereby demands a trial by jury on each and every count of his Complaint.

ALESHIRE ROBB, P.C.

By _____

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